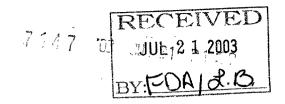


Mr. John Foret, Jr. HFS810 Harvey W. Wiley Federal Building 5100 Paint Branch Parkway College Park, MD 20740-3835



July 7, 2003

Dear Mr. John Foret, Jr.,

ImmunoKinoko™ AHCC is a dietary supplement distributed by Quality of Life Labs, Purchase, NY. The label for this product contains the following Structure/Function claims:

- ImmunoKinoko™ contains AHCC® (Active Hexose Correlated Compound), an extract obtained from a hybridization of several species of mushroom mycelia.
- AHCC supports normal immune function and may improve number and functions of immune system cells.

## **Substantiation:**

- Abe S. Preventive Effect of AHCC on Opportunistic Infection and Its Mechanism. AHCC Research Association 8<sup>th</sup> Symposium 2000.
- 2) Ahn GH. Prospective, Randomized, Clinical Evaluation of QOL & Immune Index of AHCC in Advanced Metastatic Cancer Patients. AHCC Research Association 8th Symposium 2000.
- 3) Bass NM. It could have been something I ate-functional food and the treatment of liver cancer. (Editorial) Journal of Hepatology 2002;37:147-150.
- 4) Burikhanov R, Wakame K, Igarashi Y, Wang S and Matsuzaki S. Suppressive Effect of Active Hexose Correlated Compound (AHCC) on Thymic Apoptosis Induced Dexamethasone in the Rat. *Endocrine Regulations* 2000;34:181-188.
- 5) Contreras F. Treatments of the Cancer Patients with AHCC in Oasis of Hope Hospital. Fighting Against Cancer, AHCC Research Association.
- 6) Edman J and Pescatore F. Influences of AHCC, a Combination Mushroom Extract, on Patients With Hepatitis. *Anti-Aging Medical News* 2000:11-12,14.
- 7) Ghoneum M. NK-Immunomodulation by Active Hexose Compound (AHCC) in 17 Cancer Patients. 2<sup>nd</sup> Meeting of the Society for Natural Immunity 1994.
- 8) Ghoneum M, Ninomiya Y, Torabi M, Gill G and Wojani AC. Active Hexose Correlated Compound (AHCC) Enhances NK Cell Activity of Aged Mice in Vivo. Adjuvant Nutrition in Cancer Treatment Sponsored by: American College of Nutrition & Cancer Treatment Centers of America.

Quality of Life Labs, Inc.

2700 Westchester Avenue Purchase, NY 10577 Tel: 914.251.0981 Fax: 914.251.0761

Fax 914.251.076 www.Q-O-L com 975 0162

LET 12392

85263

- 9) Ghoneum M, Wimbley M, Salem F, McKlain A, Attalah N and Gill G. Immunomodulary and Anti-Cancer Effects of Active Hemicellulose Compound (AHCC). *International Journal of Immunomotherapy* 1995.
- 10) Ghoneum M, Paul P, Ninomiya Y, Ghonaim M and Gill G. Enhancement of NK Cell Activity in Cancer Patients by Active Hemicellulose Compound (AHCC). Adjuvant Nutrition in Cancer Treatment Symposium 1992.
- Ghoneum, M. AHCC Immunotherapy in AIDS Patients. Tenth International Conference on AIDS 1994.
- 12) Hagiwara M. Preliminary report: Experience of AHCC on Progressive, Residual and Recurrent Cancer. AHCC Research Association 8th Symposium 2000.
- 13) Hosokawa M. Combination of AHCC and Chemotherapy. AHCC Research Association 8th Symposium 2000.
- 14) Ishibashi H, Ikeda T, Tansho S, Ono Y, Yamazaki M, Sato A, Yamaoka K, Yamaguchi H and Abe S. Prophylactic Efficacy of a Basidiomycetes Preparation AHCC against Lethal Opportunistic Infection in Mice. Yakugaku Zassi 2000;120(8):715-719.
- 15) Ishiguro A. Anti-Carcinogenic Activity of AHCC and PMP. The 2nd Annual Meeting of the Japanese Society for Alternative Medicine & Treatment 1999.
- Iwamoto M. A Clinical Study for AHCC on Chronic Hepatitis Patients. AHCC Research Association 8th Symposium 2000.
- 17) Iwamoto M. Effects of AHCC Administration on QOL in Cancer Patients. Fighting Against Cancer, AHCC Research Association.
- 18) Iwamoto M. Studies on the Blood Indexes from Patients of AHCC Administration. Fighting Against Cancer, AHCC Research Association.
- 19) Iwamoto M. A Discussion on Dose-Dependence of AHCC for Cancer Patients. *Fighting Against Cancer*, AHCC Research Association.
- 20) Iwamoto M. A Study on Dose-Dependence of AHCC for Cancer Patients. The 2nd Annual Meeting of the Japanese Society for Alternative Medicine & Treatment 1999.
- 21) Iwamoto M. Effects of AHCC on Diabetes By Clinical and Basic Researches The 2nd Annual Meeting of the Japanese Society for Alternative Medicine & Treatment 1999.
- 22) Kamiyama Y et al. First Department of Surgery, Kansai Medical University. Improving Effect of Active Hexose Correlated Compound (AHCC) on the Prognosis of Hepatitis C and Carcinoma Patients. The 34<sup>th</sup> Congress of the European Society for Surgical Research 1999.
- 23) Kamiyama Y, Matsui Y, Kawaguchi Y, Kosuna K and Wakame K. Clinical Experiences of AHCC. Biotherapy 2000;14(10):959-964.
- 24) Kanazawa et al. The Components in AHCC Activating Macrophage and Inhibiting Tumor Cell Proliferation. The 5th Research Association of Cancer Prevention 1998.

- 25) Kawaguchi Y, Nakagawa A and Wada J. The Utility of AHCC in Unresectable Carcinoma. Fighting Against Cancer, AHCC Research Association.
- 26) Kawaguchi Y, Teshima, Toyo H, Sugimoto N, Matsumiya M, Araki H, Komada N and Kamiyama Y. Effect of AHCC on Digestive Cancer-Especially for Terminal Cancer. AHCC Research Association 8th Symposium 2000.
- 27) Kitade H, Matsui S, Takai S, Imamura A, Kawaguchi Y, Sun B and Kosuna K. Preventive Effect of Active Hexose Correlated Compound (AHCC) on the Recurrence of Postoperative Hepatocellular Carcinoma Patients (Poster Presentation). The 33rd Congress of the European Society for Surgical Research 1998.
- 28) Kosuna K, Recent Progress of Research on AHCC; Active Hemicellulose Compound. New Food Industry 1999;41:17-23.
- 29) Kosuna K, The Development and Application of Active Hemicellulose Compound (AHCC). *Bio Industry* 1993:10.
- 30) Li Y, Matsushita K and Hosokawa M. Combination Therapy of CY and Active Hexose Correlated Compound (AHCC) Significantly Reduces the Tumor Ascites in Rats. Fighting Against Cancer, AHCC Research Association.
- 31) Luo WQ, Kanno T, Winarto A, Iwanaga T, Jun L, Futai Y, Yanahara C and Yanahara N. An Experimental Analysis of Therapeutic Effects of a Chinese Herbal Prescription in Streptozocin-Treated Rats. *Biomedical* 1998.
- 32) Matsui Y, Uhara J, Satoi S, Kaibori M, Yamada H, Kitade H, Imamura A, Takai S, Kawaguchi Y, Kwon AH and Kamiyama Y. Improved prognosis of postoperative hepatocellular carcinoma patients when treated with functional foods: a prospective cohort study. *Journal of Hepatology* 2002;37:78-86.
- 33) Matsushita K, Kuramitsu Y, Ohiro Y, Obara M, Kobayashi M, Li YQ and Hosokawa M. Combination Therapy of Active Hexose Correlated Compound Plus UFT Significantly Reduces the Metastasis of Rat Mammary Adenocarcinoma. *Anti-Cancer Drugs* 1998;9:343-350.
- 34) Matsuzaki S. Preventive Effect of AHCC on Oxidative Stress. AHCC Research Association 8th Symposium 2000.
- 35) Mukoda T, Matsumoto A and Sun B. Anti-Tumor Effects of AHCC and GCP in Hepatocarcinogenic Mice. *Biotherapy* 2001;15:24.
- 36) Mukoda T and Sun B. Protection Against Cytosine Arabinosine-Induced Alopecia By AHCC in a Newborn Rat Model. Fighting Against Cancer, AHCC Research Association.
- 37) Mukoda T, Sun B and Kosuna K. Active Hexose Correlated Compound (AHCC) Protects Against Cytosine Arabinoside Induced Alopecia in the Newborn Rat Animal Model. *Japanese Journal of Cancer Research* 1989.
- 38) Mukoda T, Wakame K and Sun B. Effect of AHCC on the Injury Induced By a Long-Term Administration of Alcohol in Mice. Fighting Against Cancer, AHCC Research Association.
- 39) Pescatore F. Role of AHCC as a Part of an Adult Disease Treatment Protocol. AHCC Research Association 8th Symposium 2000.
- 40) Rubin D. AHCC as A Novel Immunotherapy From Japan. (Independent Study)

- 41) Sun B. Improving Effect of Active Hexose Correlated Compound (AHCC) on the Liver Injury Induced By Anti-Cancer Drugs. *The 119th Meeting of the Japanese Society of Pharmacology* 1999.
- 42) Sun B. Independent Comparision of NK Activity Between MGN3 and AHCC. 2001.
- 43) Sun B. Anti-Mutagenic Effects of AHCC. The 4th Research Association of Cancer Prevention, May 1997.
- 44) Sun B, Mukoda T, Kosuna K and Okada F. 92563 Reduction of the Side Effects of Anti-Cancer Drugs By Active Hexose Correlated Compound. *Proceedings of the American Association for Cancer Research*, March 1999; Volume 40.
- 45) Sun B. Anti-Carcinogenic Effect of AHCC and Buckwheat Polyphenol. The 37th Annual Meeting of Japanese Society of Cancer Treatment 1999.
- 46) Sun B, Kanazawa T, Ono Y, Tomomi M and Kosuna K. Fractions of AHCC (Active Hexose Correlated Compound) and Their Effects on Macrophages and Tumor Cell Lines. The 57th Annual Meeting of the Japanese Cancer Association 1998.
- 47) Sun B. Improving Effect of Active Hexose Correlated Compound (AHCC) on Anemia and Alopecia Induced By Anti-Cancer Drugs. The First Annual Meeting of the Japanese Society for Alternative Medicine & Treatment 1998.
- 48) Sun B, Friedman M and Kosuna K. Effect of AHCC (Active Hexose Correlated Compound) in Both the Prevention and Treatment of Carcinomas. Critical Appraisal of Unconventional /Alternative Interventions for Carcinoma of the Prostate 1998.
- 49) Sun B, Fukuhara M and Kosuna K. Reduction of Side Effects of Anti-Cancer Drugs by AHCC, Mycelian Extracts of Cultured Basidiomycetes. *Cancer Detection and Prevention 1998*.
- 50) Sun B, Ishiguro A and Mukoda T. Reduction of Side Effects of Anticancer Drugs By AHCC Part III Liver Injury. Fighting Against Cancer, AHCC Research Association.
- 51) Sun B, Kanazawa T, Ohno Y and Mukoda T. Fractions of AHCC and Their Biological Activities. Fighting Against Cancer, AHCC Research Association.
- 52) Sun B and Mukoda T. Active Substances in Serum of Mouse Treated with AHCC. Fighting Against Cancer, AHCC Research Association.
- 53) Sun B, Wakame K, Mukoda T. Reduction of Anticancer Drugs-Induced Bone Marrow Inhibition By AHCC in Mice. Fighting Against Cancer, AHCC Research Association.
- 54) Sun B, Wakame K, Mukoda T, Toyoshima A, Kanazawa and Kosuna K. Protective Effect of AHCC on Carbon Tetrachloride Induced Liver Injury in Mice. Fighting Against Cancer, AHCC Research Association.
- 55) Sun B, Mukoda T, Miura T, Fujii H, Yuan L and White RD. Anti-tumor Effects of the Combination of Genistein Concentrated Polysaccharide (GCP) and Active Hexose Correlated Compound (AHCC). *Biotherapy* 2001;15(3):379-382.
- 56) Sun B, Shi X, White RW, Hackman RM. Synergistic Antitumor Effects of Mushroom Polysacchrides (AHCC) and Aglycone Isoflavones (GCP) on Prostate and Other Cancers. *Proceedings of the American Association of Cancer Research* 2001.

- 57) Sun B, Wakame K, Mukoda T, Toyoshima A, Kanazawa T and Kosuna K. Preventive Effects of AHCC on Carbon Tetrachloride Induced Liver Injury in Mice. *Natural Medicine* 1997;51(4):310-315.
- 58) Sun B. The Benefits of the Combination of GCP and AHCC in Cancers. AHCC and GCP Research Association 2002.
- 59) Takahashi K, Kawaguchi Y, Matsui Y and Kamiyama Y. AHCC Treatment for the Peritonitis Carcinomas Patients. Fighting Against Cancer, AHCC Research Association.
- 60) Takemori N. Changes of Mouse Omental Milky Spots By Peritoneal Injection of AHCC: Light Microscope, Electron Microscope and Limmunohistochemical Examination. Fighting Against Cancer, AHCC Research Association.
- 61) Tasaki S, Kamiyama Y, Matsui Y, Inui H, Satoi S, Imamura A, Nakamura K, Nakamoto H, Uetsuji S, Kanazawa T and Sun B. The Experiences Using AHCC to Treat Gastrointestinal and Breast Cancers in Fujimoto Hospital. Fighting Against Cancer, AHCC Research Association.
- 62) Toyosima S, Nakagawa A, Komada N, Toyokawa H and Kawaguchi Y. The Experiences Using AHCC to Treat Gastrointestinal and Breast Cancers in Fujimoto Hospital. . *Fighting Against Cancer*, AHCC Research Association.
- 63) Uno K, Housakawa G and Ueda Y. Impaired Th-1 Related Immune System in Cancer Patients Comparable Down-Regulation in Early Stage and Advanced Stage. *Adjuvant: Nutrition in Cancer Treatment Symposium*.
- 64) Uno K, Kosuna K, Sun B, Fujii H, Wakame K, Chikumaru S, Hosokawa G and Ueda Y. Active Hexose Correlated Compound (AHCC) Improves Immunological Parameters and Performance Status of Patients With Solid Tumors. *Biotherapy* 2000;14(3):303-309.
- 65) Uno K. The Introduction of Immunological Parameters to the Screening of Cancer. The 2nd Annual Meeting of the Japanese Society for Alternative Medicine & Treatment 1999.
- 66) Wakame K, Mukoda T and Sun B. Effect of Active Hexose Correlated Compound (AHCC) in Diabetic Rats. Fighting Against Cancer, AHCC Research Association.
- 67) Wakame K. Protective Effects of Active Hexose Correlated Compound (AHCC) on the Onset of Diabetes Induced by Streptozotocin in the Rat. *Biomedical Research* 1999;20(3): 145-152.
- 68) Wang S, Ichimara K and Wakame K. Preventive Effects of Active Hexose Correlated Compound (AHCC) on Oxidative Stress Induced by Ferric Nitrilotriacetate in the Rat. *Dokkyo Journal of Medical Sciences* 2001;28(2-3):745-752.
- 69) Wang S, Wakame K, Igarashi Y, Kosuna K and Matsuzaki S. AHCC on Immobilization Stress in the Rat: Beneficial Effects of Active Hexose Correlated Compound. *Dokkyo Journal of Medical Sciences* 2001;28(1):559-565.
- 70) Yagita A. Administration of BRMS to Patients With Different Sensitivities. *The 5th AHCC Research Conference 1998*.
- 71) Yagita A. Clinical and Basic Studies on the Oral Administration of AHCC (Active Hexose Correlated Compound), as a Human Natural IL-12 Inducer, For Progressive and End-Stage Cancer Patients. Fighting Against Cancer, AHCC Research Association.

- 72) Yamazaki M. Protective Effect of AHCC on Galactosamine Induced Hepatitis in Mice. Fighting Against Cancer, AHCC Research Association.
- 73) Yuan L, Fuji H, Sato E, Sun B and Hosokawa M. Expression of Cytokines in Normal and Tumor-Bearing Mice Treated with AHCC and its Fractions. *Fighting Against Cancer*, AHCC Research Association.
- 74) Yui S and Yamazaki M. Inhibitory Effects of Sera After AHCC Treatment in Mice on Cancer Cell Proliferation. *Fighting Against Cancer*, AHCC Research Association.
- 75) Yui S and Yamazaki M. Effect of AHCC on Diabetes Induced By Streptozotocin (STZ) in Mice. Fighting Against Cancer, AHCC Research Association.

If you have any questions or need additional information, please contact me at (914) 251-0701 ext.129.

Sincerely.

Kristin A. Schierenbeck, MS, CNS

Senior Technical Manager Certified Nutrition Specialist

Quality of Life Labs